ISRCTN85021654 https://doi.org/10.1186/ISRCTN85021654

Can diagnostic ultrasound distinguish between the function of the trunk stabilising muscles of patients with chronic non-specific Low Back Pain and healthy controls?

Submission date
14/12/2006

Recruitment status
No longer recruiting

Registration date
26/01/2007

Overall study status
Completed

Last Edited
04/11/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Haiko Sprott

Contact details
Department of Rheumatology and Institute of Physical Medicine
University Hospital Zurich
Gloriastrasse 25
Zurich
Switzerland
CH-8091
haiko.sprott@usz.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EK 527

Study information

Scientific Title

Acronym
TDI in LBP

Study objectives
Tissue doppler ultrasound as a non-invasive method should be able to distinguish between the function of the trunk stabilising muscles of patients with chronic non-specific low back pain and healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Zurich (Switzerland) approved of the study on the 1st September 2005 (ref: 527) of the KEK. This was an amendment of an ongoing study since October 2004.

Study design
Comparison of cohorts

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Unspecific chronic low back pain

Interventions
The ability to voluntarily activate the deep trunk muscles can be visualised reliably and accurately in the clinical environment using real-time functional ultrasound (M-mode). This will serve as the basis for assessment of the patients in the present study. The thickness changes of the deep trunk muscles will be assessed using the procedure described by Richardson et. al., which takes about 15 to 30 minutes to complete.

The measurements will be made using a Philips HDI 5000 ultrasound machine with a linear array transducer (5 - 12 MHz). The transducer will firstly be fixed in a custom-made foam block to prevent tilting and to control the pressure applied during the assessment. It will then be positioned at a point 2.5 cm anteromedial to the mid-point between the iliac crest and the costal margin on the mid-axillary line, where the fascial boundaries of the Transversus Abdominis (TA), Internal Oblique (IO) and External Oblique (EO) lie parallel. A gel standoff pad (Sonar Aid) and transmission gel will be placed between the transducer head and the skin to permit good signal transmission. To minimise the relative movement between the transducer and the abdomen, the foam block will be fixed around the abdomen using Velcro straps.

Measurements will be made with the patient firstly in a supine position, with a relaxed abdomen (and with hips flexed to 45°and knees flexed to 90°), and then during the performance of a stomach drawing-in exercise (abdominal hollowing), with the contraction being held for at least ten seconds. The patients will firstly receive instructions on how to perform the test-exercise and will be given a short time to practice before the instrumentation is attached and the measurements begin.

Five trials will be carried out on each of the right and left sides. All scanner settings for the ultrasound will be kept constant except for the depth, focus and gain, which will be adjusted for each individual to permit optimal ultrasound quality. M-mode grey-scale images, superimposed with Tissue Doppler Imaging (TDI) signals, will be sampled at approximately 300 Hz and exported to the computer to which the ultrasound machine is interfaced, for off-line analyses.

HDI-Lab (an analysis programme provided by Philips for research purposes only) will be used for determination of abdominal muscle thickness changes during the test contractions. The fascial boundaries of the muscles of interest are firstly marked with a cursor at regular intervals along the full length of the M-mode image, in order to guide an edge-detection programme. The latter takes advantage of the TDI velocity information to derive the displacement of a given point between two adjacent M-mode columns (displacement being equal to tissue velocity multiplied by the time difference between adjacent M-mode columns).

Once the fascial borders have been identified, the vertical distance between two fasciae (i.e. the muscle thickness) for every sampling point in time (i.e., every 0.003 s), and for each muscle, is then calculated and exported as a text file into Excel. From here, a custom-made programme written in Labview is used to identify the resting muscle thickness (average over a one second period prior to contraction), the maximum TA thickness (maximum average value over any given three second period during the test contraction) and the IO and EO thicknesses at the point of maximum TA thickness. The proportional increase in TA thickness and the concomitant changes in IO and EO thicknesses will be used to classify the ability to selectively activate TA.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes in TDI values

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2004

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Between 18 and 65 years old
2. Average pain intensity over the last two weeks more than or equal to three and less than or equal to eight on the zero to ten Visual Analogue Scale (VAS)
3. Recurrent or continual episodes of Low Back Pain (LBP) with or without referred pain (of a non-radicular nature) for at least three months, serious enough to cause absence from work or solicitation of medical attention
4. Ability and willingness to travel independently to the Unversity Hospital Zurich (UniversitätsSpital Zürich) (USZ) for assessment
5. Fluency in the German or English languages (spoken and reading comprehension)
6. Willingness to comply with the study protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
23 patients and 23 matched healthy controls

Key exclusion criteria
1. General:
a. constant or persistent severe pain
b. non-mechanical LBP
c. pregnancy
2. Neural tissue involvement:
a. current nerve root entrapment accompanied by neurological deficit
b. spinal cord compression
c. tumours
d. other corresponding disorders (suspicion of these upon initial clinical examination [red flags] will require confirmation by Magnetic Resonance Imaging [MRI]; otherwise no MRI will be carried out)
3. Disorders of the spine:
a. severe instability (spondylolisthesis grade three or higher)
b. severe osteoporosis (height loss of more than 4 cm since the age of 20)

c. severe structural deformity (rigid scoliosis in clinical examination, flexion movements)
d. systemic inflammatory disease (if any of these are suspected, based on the clinical examination, X-ray and other specialised imaging will be carried out; otherwise no X-ray imaging will be done)
e. previous spinal fusion or failed surgery
4. Other diseases which contraindicate exercise training:
a. severe cardiovascular diseases (New York Heart Association [NYHA] III and IV)
b. decompensated metabolic diseases
c. any other corresponding disorders preventing active rehabilitation
d. acute infection
e. recent (in the last three months) major operation
f. lack of co-operation
g. uncontrolled alcohol or drug abuse
h. decompensated psychopathological diseases

Date of first enrolment
01/10/2004

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Switzerland

Study participating centre
Department of Rheumatology and Institute of Physical Medicine
Zurich
Switzerland
CH-8091

Sponsor information

Organisation
Swiss National Science Foundation (Switzerland)

Sponsor details
Address Headquarters
Wildhainweg 3
P.O. Box 8232
Berne
Switzerland
CH-3012
bflueckiger@snf.ch

Sponsor type
Research organisation

Website
http://www.snf.ch/default_en.asp

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Research organisation

Funder Name
Supported by a grant from the Swiss National Research Program (NRP 53 - 'Musculoskeletal Health - Chronic Pain') of the Swiss National Science Foundation (Switzerland) (project ref: 405340-104787/2).

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration